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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/739,223	12/18/2000	Gerald Batist	701826-05008-CIP	3120

7590 11/20/2003

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EXAMINER
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CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/739,223

Applicant(s)

BATIST ET AL.

Examiner

Shin-Lin Chen

Art Unit

1632

--Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 1-20 and 23-25.

Claim(s) withdrawn from consideration: 21 and 22.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

Shin-Lin Chen  
Primary Examiner  
Art Unit: 1632

Continuation of 2. NOTE: Claims 26-31 are drawn to a method of screening for tumor-specific expression of a gene in vitro by introducing a construct comprising the rat Hex II promoter to a sample of cells and screening said sample of cells for selective expression of said gene. Claims 26-31 are drawn to a distinct invention from the elected invention that was examined, therefore, claims 26-31 will be withdrawn from consideration if entered. Further, the phrase "said tumor" in claim 28 lack antecedent basis and raise new 112 second paragraph issue..

Continuation of 3. Applicant's reply has overcome the following rejection(s): 35 U.S.C. 102(b) and 103(a) rejections if the amendment is entered.

Continuation of 5. does NOT place the application in condition for allowance because: Applicants argue that the in vivo success of the claimed method is described in Figs. 6A-6H and 7A and page 31 lines 12-31 describes the utility of the claimed method (amendment, p. 4). this is not found persuasive because of the reasons of record. Example I of the present invention teaches intratumoral injection of the expression vector expressing Tk protein but fails to provide enabling evidence for tumor-specific activity of the Hex II promoter and reduction in tumor volume via various administration routes in vivo other than intratumoral injection. This is a 35 U.S.C. 112 first enablement rejection, the argument regarding the utility of the claimed invention is confusing and is irrelevant to the enablement rejection